

AMENDMENTS TO THE CLAIMS

1. (Currently Amended). An orally dissolving, hard boiled, dosage form useful for transmucosal oral administration of an nicotine active agent, comprising:
 - a) a glassy matrix comprising at least one substantially non-hygroscopic sugar alcohol capable of forming a glassy structure;
 - b) a water soluble gelling gum in an amount sufficient to provide an oral dissolution rate of said glassy matrix such that a desired amount of said active agent is delivered via the oral mucosa prior to ingestion into the stomach; and
 - c) said nicotine active agent,wherein said active agent is substantially contained within said glassy matrix.
2. (Original). The dosage form of claim 1 wherein said active agent is one or more selected from the group consisting of drugs, cold agents, cough agents, throat agents, vitamins, zinc, menthol, eucalyptus, hexylresorcinol, caffeine, tooth whitening agents, anti-plaque agents, breath freshening agents and nicotine.
3. (Original). The dosage form of claim 2 wherein said active is a nicotine active agent.
4. (Original). The dosage form of claim 1 wherein said water soluble gelling gum is one or more selected from the group consisting of xanthan gum, guar gum, gum arabic, alginates and carageenan.
5. (Original). The dosage form of claim 4 wherein said gum is xanthan gum.
6. (Original). The dosage form of claim 3 wherein said dissolution rate is sufficient to provide that at least 50% of said nicotine is delivered via the oral mucosa prior to ingestion into the stomach.
7. (Original). The dosage form of claim 6 wherein at least 75% of said nicotine is delivered via the oral mucosa.
8. (Previously Amended). The dosage form of claim 1 wherein said gum is present in an amount sufficient to provide that said dosage form dissolves orally over a period of about 10 to 15 minutes.

9. (Currently Amended). The dosage form of claim 1 wherein said water soluble gelling gum is present in an amount of from about 0.5 to about 5.0 percent by weight.

10. (Currently Amended). The dosage form of claim 9 wherein said water soluble gelling gum is present in an amount of from about 1.0 to about 4.0 percent by weight.

11. (Currently Amended). The dosage form of claim 10 wherein said water soluble gelling gum is present in an amount of from about 1.0 to 3.5 percent by weight.

12. (Previously Amended). The dosage form of claim 1 wherein the sugar alcohol comprises a mixture of 1,6-GPS (6-O- α -D-glucopyranosyl-D-sorbitol) and 1,1-GPM (1-O- α -D-glucopyranosyl-D-mannitol) in a weight ratio of from about 99:1 to about 1:99.

13. (Previously Amended). The dosage form of claim 1 comprising at least about 50% of the sugar alcohol, based on the weight of the dosage form.

14. (Previously Amended). The dosage form of claim 13 comprising at least about 70% of the sugar alcohol mixture, based on the weight of the dosage form.

15. (Previously Amended). The dosage form of claim 14 comprising at least about 85% of the sugar alcohol mixture, based on the weight of the dosage form.

16. (Cancelled).

17. (Currently Amended). The dosage form of claim 16 wherein the nicotine active is selected from nicotine oil, nicotine bitartrate, nicotine polacrilex and combinations thereof.

18. (Previously Amended). The dosage form of claim 1 comprising from about 0.5 mg to about 5 mg of the nicotine active per dosage unit.

19. (Previously Amended). The dosage form of claim 12 wherein the sugar alcohol comprises a mixture of 1,6-GPS and 1,1-GPM in a weight ratio of from about 70:30 to about 30:70.
20. (Previously Amended). The dosage form of claim 12 wherein the sugar alcohol comprises a mixture of 1,6-GPS and 1,1-GPM in a weight ratio of from about 60:40 to about 40:60.
21. (Previously Amended). The dosage form of claim 12 wherein the sugar alcohol mixture is ISOMALT.
22. (Previously Amended). The dosage form of claim 1 further comprising a buffer in an amount effective to provide an alkaline mouth saliva pH.
23. (Previously Amended). The dosage form of claim 22 wherein the buffer is selected from sodium carbonate, sodium bicarbonate, calcium carbonate, potassium carbonate, potassium bicarbonate, sodium phosphate dibasic, sodium phosphate tribasic, potassium phosphate dibasic, potassium phosphate tribasic, and combinations thereof.
24. (Previously Amended). The dosage form of claim 23 wherein the buffer is selected from sodium carbonate, potassium carbonate, and combinations thereof.
25. (Previously Amended). The dosage form of claim 1 wherein the glassy matrix further comprises from about 1% to about 20%, based on the weight of the dosage form, of one or more compounds selected from the group consisting of sucrose, sorbitol, and xylitol.
26. (Previously Amended). The dosage form of claim 3 further comprising a non-pharmacological component for providing a sensory signal effective to provide rapid nicotine craving relief.
27. (Previously Amended). The dosage form of claim 3 wherein the dosage form is a lozenge.
28. (Original). A method of reducing nicotine cravings comprising orally administering a dosage form of claim 3 to a person in need of nicotine craving reduction.

29. (Previously Amended). The method of claim 28 wherein a nicotine active blood plasma concentration of at least about 6 ng/ml is achieved after starting oral administration of the dosage form.

30. (Previously Amended). The method of claim 29 wherein a sustained nicotine active blood plasma concentration of from about 6 ng/ml to about 35 ng/ml is achieved after starting oral administration of the dosage form.

31. (Original). A method of reducing tobacco usage comprising orally administering a dosage form of claim 3 to a person in need of reducing tobacco usage.

32. (Previously Amended). A dosage form useful for transmucosal oral administration of a nicotine active, wherein the dosage form provides a nicotine active blood plasma concentration of at least about 6 ng/ml after starting oral administration of the dosage form, wherein the dosage form is an orally dissolving, hard boiled, lozenge comprising a glassy matrix comprising at least one substantially non-hygroscopic sugar alcohol capable of forming a glassy structure; a water soluble gelling gum in an amount sufficient to provide an oral dissolution rate of said glassy matrix such that a desired amount of said active agent is delivered via the oral mucosa prior to ingestion into the stomach; and said active agent; wherein said active agent is substantially contained within said glassy matrix.

33. (Cancelled).